



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Burkly et al.

Serial No: 09/804,490

Filed: March 12, 2001

For: Hedgehog and Patched Antagonists  
for Inhibiting Cell and Tissue Growth  
and Differentiation and Uses Therefor

Attorney Docket No. CIBT-P01-114

Conf. No.: 2374

Art Unit: 1649

Examiner: John D. Ulm

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

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July 18, 2008

Date of Signature  
and of Mail Deposit

Pamela Harrison  
Pamela Harrison

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**

MS Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.705(b), Applicants hereby request reconsideration of the patent term adjustment indicated in the Notice of Allowance for the above referenced application. At allowance, the patent was granted a 278 day patent term adjustment. However, as outlined below, Applicants believe that this calculation included both errors that result in an award of more patent term adjustment than Applicants are entitled and errors that deprive Applicants of days of patent term adjustment. Upon review, Applicants believe that the correct patent term adjustment is 510 days and Applicants respectfully request review and reconsideration.

## I. Possible Errors That Could Reduce Patent Term Adjustment

- A Final Office Action was mailed March 9, 2005. In response, Applicants filed a Request for Continued Examination which was received by the Office August 4, 2005. The Office's PTA calculation does not appear to have accounted for the period of time in excess of three months taken to reply to this Final Office Action. 37 CFR 1.704(b). As such, Applicants believe that the patent term adjustment is reduced by 56 days.
- On December 13, 2007, Applicants filed a Request for Continued Examination. On January 11, 2008, Applicants filed a Supplemental response. The Office's PTA calculation does not appear to have accounted for the filing of this Supplemental response. 37 CFR 1.704(c)(8). As such, Applicants believe that the patent term adjustment is reduced by 28 days.
  - Applicants note that there appears to be an error in the Transaction History tab available via PAIR regarding the above referenced portion of the file history. Although the Image File Wrapper tab reflects that this RCE was received December 13, 2007, the Transaction History tab indicates that the RCE was received January 11, 2008. Appropriate correction of the record is requested.
- On March 5, 2008, Applicants filed a Supplemental response (an Information Disclosure Statement). The Office's PTA calculation does not appear to have accounted for the filing of this Supplemental response. 37 CFR 1.704(c)(8). Specifically, the Office's PTA calculation does not appear to have accounted for the period of time between the January 11, 2008 Supplemental response and the March 5, 2008 Supplemental response. As such, Applicants believe that the patent term adjustment is reduced by 53 days.
- Applicants filed an amendment under 37 CFR 1.312 on June 5, 2008. A response to Applicants' amendment was mailed June 13, 2008. The Office's PTA calculation does not appear to have accounted for the period of time between the filing of Applicants' amendment after allowance and the Office's response. 37 CFR 1.704(c)(10). As such, Applicants believe that the patent term adjustment is reduced by 9 days.

The above are the possible errors in calculation of patent term adjustment of which Applicants are aware that, if corrected, could reduce patent term adjustment. Applicants invite the Office to reconsider and independently reevaluate its calculation of patent term adjustment.

Applicants respectfully submit that the instant petition itself does not constitute a failure to engage in reasonable efforts to conclude processing or examination of an application. Applicants' petition is timely and fully compliant with 37 CFR 1.705(b). As such, the filing of the instant petition does not and should not result in reduction of patent term adjustment. 37 CFR 1.704(e).

## II. Possible Errors for Which Additional Patent Term Adjustment Is Requested

- A Restriction Requirement was mailed October 2, 2003. Applicants filed a reply that was received by the Office on October 27, 2003. However, this reply was not matched to the file until Applicants provided the Examiner with a copy of the reply and the stamped post card receipt showing that the Office received the original reply October 27, 2003 (a copy of the original stamped postcard receipt and the paper providing a copy to the Examiner are enclosed herewith as Exhibit 1). Despite the presence in the Image File Wrapper of Interview Summaries detailing the failure to match the original reply with the file, and despite Applicants' stamped postcard receipt evincing the timely filing and receipt of the original reply, the Transaction History tab in PAIR indicates May 11, 2004, rather than October 27, 2003, as the date upon which the reply to the action was received. Applicants submit that this represents an error and that Applicants should not be assessed a 130-day reduction in patent term adjustment associated with the filing of a reply in excess of three months from the mailing date of the action. Applicants timely replied to the October 2, 2003 action. Accordingly, Applicants request that the patent term adjustment be increased by 130 days.
  - Applicants request correction of the Transaction History to reflect that a response to the October 2, 2003 action was received October 27, 2003.
  - Applicants note that the Transaction History does reflect the date on which the Office received a copy of Applicants' original reply (May 11, 2004), as

well as interview summaries from the Examiner and Applicant describing the misfiling of the original response and the Examiner's request that Applicants provide a copy of the response. These supplemental papers were submitted at the request of the Examiner. As such, Applicants do not believe that these supplemental papers reduce patent term adjustment.

- As noted above, the Transaction History tab in PAIR indicates May 11, 2004 as the date upon which Applicants replied to the October 2, 2003 Restriction Requirement. However, as evidenced by Applicants' stamped postcard receipt (See Exhibit 1), Applicants filed a reply that was received by the Office on October 27, 2003. As such, regardless of whether the Office misplaced Applicants' reply, the October 27, 2003 date is the date that should be used for calculating patent term adjustment under 37 CFR 1.702(a)(2) based on the failure of the Office to respond to a reply under 35 U.S.C. 132 within four months after the date on which the reply was filed. Following Applicants' October 27, 2003 reply, the next action from the Office was a Non-Final Office Action mailed September 7, 2004. The Office's patent term adjustment calculation has not taken this delay into account. In accordance with 37 CFR 1.703(a)(2), Applicants are entitled to the period beginning on the day after the date that is four months after the date a reply under 1.111 was filed and ending on the date of mailing of an action under 35 U.S.C. 132 [e.g., February 28, 2004 to September 7, 2004]. Accordingly, Applicants request that the patent term adjustment be increased by 192 days.

Applicants note for the record and in compliance with 37 CFR 1.705 that (i) this patent is not subject to a terminal disclaimer [37 CFR 1.705(b)(2)(iii)] and (ii) the fee set forth for filing this petition is provided for herewith [37 CFR 1.705(b)(1)].

### III. Summary

In view of the above referenced errors, Applicants request reconsideration of the patent term adjustment for the above referenced application. Applicants believe that the patent term

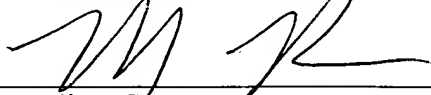
adjustment should rightfully be increased by an additional 232 days, for a total adjustment of 510 days.

**Conclusion**

Applicants believe no fee is due with this response, other than the petition fee set forth in 37 CFR 1.18(e) and provided for on the accompanying fee transmittal. However, if any additional fee is due, please charge our **Deposit Account No. 18-1945, under Order No. CIBT-P01-114** from which the undersigned is authorized to draw.

Date: July 18, 2008

Respectfully Submitted,



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Melissa S. Rones  
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Boston, MA 02110  
Phone: 617-951-7000  
Fax: 617-951-7050



Via: First Class Mail		Atty Dkt No.: CIBT-P01-114
Inventor: Burkly et al.		
Application No.: 09/804490		Filing Date: March 12, 2001
Title: HEDGEHOG AND PATCHED ANTAGONISTS FOR INHIBITING CELL AND TISSUE GROWTH AND DIFFERENTIATION AND USES THEREFOR		

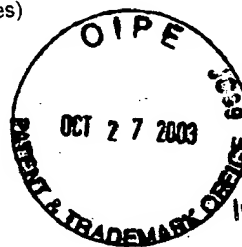
Documents Filed:  
Reply to Restriction Requirement (2 pages)

This return postcard

Via: First Class Mail		Atty Dkt No.: CIBT-P01-114
Inventor: Burkly et al.		
Application No.: 09/804490		Filing Date: March 12, 2001
Title: HEDGEHOG AND PATCHED ANTAGONISTS FOR INHIBITING CELL AND TISSUE GROWTH AND DIFFERENTIATION AND USES THEREFOR		

Documents Filed:  
Reply to Restriction Requirement (2 pages)

This return postcard



Ropes & Gray

NOV 03 2003

Intellectual Property Dept.

Sender's Initials: MSR/gb	Date: October 24, 2003
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re Application of:  
Burkly et al.

Serial No: 09/804,490

Filed: March 12, 2001

For: Hedgehog and Patched Antagonists  
for Inhibiting Cell and Tissue Growth  
and Differentiation and Uses Thereof

Attorney Docket No. CIBT-P01-114

Art Unit: 1642

Examiner: M. Brannock

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and of Mail Deposit

  
Ginny Blundell

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY TO RESTRICTION REQUIREMENT**

Sir:

In reply to the outstanding Restriction Requirement, mailed October 2, 2003, in connection with the above application, Applicants hereby elect with traverse Group I, drawn to hedgehog antibody antagonists and methods of treating cells or animals therewith. Applicants elect this invention with traverse, because claims 1, 5, 9, 13-20, and 24 encompass overlapping subject matter based on use of hedgehog antagonists. Accordingly, searches related to these hedgehog antagonists are co-extensive, and Groups I-III could be examined simultaneously without significant additional burden.

In addition, Applicants submit that claims 1, 5, 9, 13-20, and 24 are linking claims for Groups I-III. Applicants respectfully remind the Examiner that, in accordance with MPEP 809, "should any linking claim be allowed, the restriction requirement must be withdrawn."

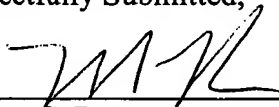
REMARKS

Claims 1-28 constitute the pending claims in the present application, and Applicants elect with traverse inventions of Group I. If any clarification of the above response would facilitate prosecution of this application, Applicants respectfully request that the Examiner contact the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: October 24, 2003

**Customer No: 28120**  
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Boston, MA 02110  
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Respectfully Submitted,

  
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Melissa S. Rones  
Reg. No. 54,408





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To: Examiner M. Brannock	U.S. Patent and Trademark Office	(703) 872-9306	

From: Melissa S. Rones, Ph.D.

Re : U.S. Serial No. 09/804,490	Attorney Docket No.: CIBT-P01-114
Inventor: Burkly et al.	Art Unit 1642
Filed: March 12, 2001	Examiner: M. Brannock
Title: HEDGEHOG AND PATCHED ANTAGONISTS FOR INHIBITING CELL AND TISSUE GROWTH AND DIFFERENTIATION AND USES THEREOF	

Comments: Attached are:

Further Communication (2 pages)  
Copy of Reply to Restriction Requirement filed on 10/24/03 (2 pages)  
Copy of the PTO, stamped-returned postcard for 10/24/03 filing (1 page)

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**PLEASE COMPLETE WHEN SUBMITTING TO FAX DEPARTMENT**

Date: May 11, 2004

Time: 12:58 PM

File Symbol: CIBT-P01-114

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Submitted By:

Phone:

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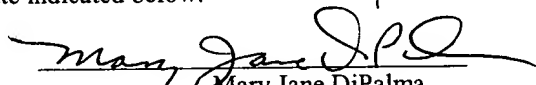
Examiner: M. Brannock

**CERTIFICATE OF FACSIMILE**

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May 11, 2004

Date of Signature  
and of Mail Deposit

  
Mary Jane DiPalma

**FURTHER COMMUNICATION**

Sir:

The Examiner in this case recently informed us that Applicants' response to the outstanding Restriction Requirement in this case was not received. Accordingly, Applicants enclose herewith a copy of the reply filed October 24, 2003, as well as the stamped, return postcard.

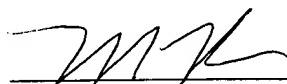
### CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Applicants believe that no fee is due as the response to the outstanding Restriction Requirement was timely filed. However, should an extension of time or other fee be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,

Date: May 11, 2004

**Customer No: 28120**  
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One International Place  
Boston, MA 02110  
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Fax: 617-951-7050



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Melissa S. Rones  
Reg. No. 54,408



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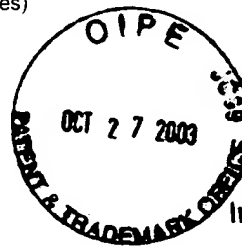
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Ropes & Gray

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